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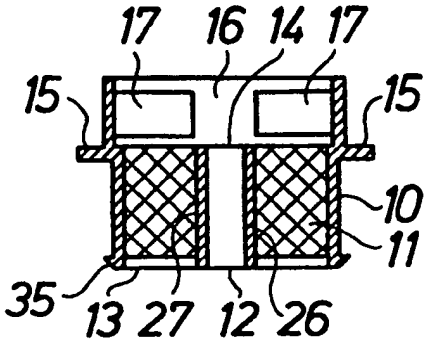
(57) Abstract

Device to be fitted in a tracheostoma, comprising a filter housing (10) for receiving a moisture and heat exchanging filter (11) said filter housing having a first opening (12) to be connected to the patient's stoma and at least one second opening (14) at the opposite side of the filter (11). According to the invention there is provided at said second opening (14) of the filter housing (10) a valve member for closing said second opening, said valve member being adapted to be manually closed by means of a finger and to be opened by returning resiliently.



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TRACHEOSTOMA DEVICE

The invention relates to a device to be fitted in a tracheostoma, comprising a filter housing for receiving a moisture and heat exchanging filter, said filter housing having a first opening to be connected to the patient's stoma and at least one second opening at the opposite side of the filter in the flow direction of the breathing air.

Due to disease it is sometimes necessary to remove by surgery the larynx (laryngectomy). In order that breathing will still be possible a so called tracheostoma must be opened at the outside of the throat.

In connection with laryngectomy also the ability to talk is lost because the vocal cords must be excised at the surgery, and in order to restore to some extent the ability to talk it is possible to open by surgery a fistula between esophagus and trachea for the passage of air to the oral cavity. In the fistula a so called voice valve is fixed, and provided that the tracheostoma is blocked the patient can force air through the voice valve and thus induce vibrations in the upper portion of the esophagus and in that way produce acceptable talk.

Voice valves of this type are disclosed i.a.in SE-B-463 649, SE-A-8904365-7, US-A-4 614 516 and US-A-5 064 433. It is necessary when using these valves that the patient in some way covers the tracheostoma for example by one or more fingers. However, this causes some inconvenience to the patient i.a. due to the fact that the stoma often is coated by secretion and can have an irregular shape and thus is difficult to cover. After laryngectomy the generation of secretion moreover increases, and further symptoms of irritation may arise due to the function of the nose being lost. Another serious

drawback is that the patient is troubled by the appearance of the stoma and wishes to conceal it.

Another way of blocking the stoma is to use voice or stoma valves wherein an accelerating flow of air initiates closing of the valve. Embodiments of such valves are disclosed i.a. in US-A-5 059 208, US-A-4 582 058 and US-A-4 325 366. The drawback of these valves is that the high pressure which is sometimes necessary for talking forces the valve to come loose from the throat. It is also difficult for some patients to generate the air shock necessary in order to close the valve. These devices moreover often are not very attractive aesthetically due to the dimensions thereof which make it difficult to conceal the devices under garments.

By laryngectomy the patient looses the moisture and heat exchanging function as well as the filtering function obtained when the breathing air passes through the oral and nasal cavities with the result that the inhalation air often is felt to be too dry, cold and entrained by particles. In SE-B-466 990, SE-B-467 125 and SE-B-467 289 there are disclosed so called breating protections having a filter which absorbs the moisture and heat of the exhalation air. In order to make possible some kind of talk these devices must be covered by the fingers the drawback of secretion thus still remaining.

The purpose of the invention is to overcome the drawbacks and shortcomings mentioned above of prior art devices used in tracheostomas and to provide a manually controlled device having filter and valve function as well as moisture and heat exchanging function.

The purpose mentioned above is achieved by the device of the invention having obtained the characterizing features of claim 1.

The invention will be explained in more detail by illustrative embodiments reference being made to the accompanying drawings in which

FIG. 1 is a longitudinal cross-sectional view of a portion of a device according to the invention,

FIG. 2 is a perspective view of a valve member for the device according to the invention,

FIG. 3 is a longitudinal cross-sectional view of an alternative embodiment of the device according to the invention,

FIG. 4 is a longitudinal cross-sectional view of a further alternative embodiment of the device according to the invention,

FIG. 5 is a longitudinal cross-sectional view of a holder for the device according to the invention, and

FIG. 6 is a longitudinal cross-sectional view of a holder for the device according to the invention.

The device according to the invention as shown in FIGS. 1 and 2 comprises a cylindrical filter housing 10 in which a moisture and heat exchanging filter 11 is received. The filter housing 10 has a first opening 12 wherein radial arms 13 form a stop element for the filter 11. At the opposite side of the filter 11 a second opening 14 is provided in the filter housing 10, at which a radially projecting outside annular flange 15 is provided. A rim 16 forms an extension of the filter housing 10 on the outside of the flange 15. Apertures 17 for breathing air are provided in the rim 16.

A valve member comprises a lid 18 having a central pin 19 which at one end thereof has a bead 20 and forms a slot 21, and a spring 22 shaped as a cross having a central annular portion 23. One pair of radially opposite arms 24 of the cross are plane while the other pair of radially opposite arms 25 are curved. In the filter housing 10 the radial arms 13 are connected centrally with a tubular

holder 26 which extends coaxially in the filter housing 10 to receive therein the pin 19.

When the device of the invention is being used the filter 11 is located in the filter housing 10 so that the latter will engage the radial arms 13 the holder 26 being received in a passage 27 in the filter which thus encircles the holder 26. The spring 22 is located on the filter so that one pair of arms 24 will engage the filter and the other pair of arms 25 will be curved upwards away from the filter 11. The pin 19 of the lid 18 will be received in the central annular portion 23 of the spring and the holder 26, the bead 20 retaining the pin 19 in the holder 26.

In order to generate talk the lid 18 is exposed to a light pressure from a finger until the lid covers said second opening 14. The device can be closed in this manner even if it is covered by garments. At the same time the device is prevented from coming loose from the stoma because it is pressed against the throat by the finger during talking. The spring 22 due to the shape thereof holds the filter 11 in position and also acts as a return spring so that the lid 18 after the pressure having been relieved will resiliently return to the starting position thereof. The rim 16 reduces the risk of the valve member being inadvertently closed for some reason or other, and since the starting position of the lid 18 is spaced from the filter 11 breathing air can pass through the apertures 17 when the device is open, i.e. when the lid 18 is in the outer non-actuated position thereof.

In FIGS. 3 and 4 two alternative embodiments of the device of the invention are shown. The valve member in FIG. 3 comprises a spring element 28 of an elastic material, which collapses and seals when pressed down towards the opening 14, for example by means of a finger. Alternatively the valve member can comprise a flap 29, FIG. 4, which can

be pressed resiliently towards the opening 14 of the device.

In FIGS. 5 and 6 there are shown alternative embodiments 30 and 31 of the holder of the device according to the invention. The holder 30 comprises an intermediate piece 32 and an inside raised portion 33, an outside projecting annular flange 34 being provided at one end of said piece. After application to the tracheostoma the flange 34 shall engage the outside of the throat and be attached by means of tape. The device of the invention is then inserted into the holder 30 and is retained therein by the filter housing 10 at said first opening 12 has an outside bead 35 engaging the raised portion 33 and also functioning as a seal at the stoma. Alternatively, there may be provided at said first opening 12 a groove for engagement with a bead in the holder 30. The holder 31 is intended to be applied to the tracheostoma on the inside of the trachea and comprises an intermediate piece 36 having an inside raised portion 37 and an outside projecting annular flange 38 spaced from one end. This flange 38 is intended to engage the outside of the throat and can be attached by means of tape.

The device according to the invention is intended to be a one-way product which easily can be replaced at low cost after having been used for a predetermined period. The material of the device therefore suitably is a plastic material. For example the filter housing 10 and the lid 18 as well as the pin 19 can be made of polypropylene or polyethylene. The spring preferably is made of acetaldehyde resin, for example DELRIN, while the filter preferably consists of foamed polyurethane impregnated with litium chloride or potassium chloride in order to increase the moisture and heat exchanging ability of the filter.

CLAIMS

1. Device to be fitted in a tracheostoma, comprising a filter housing (10) for receiving a moisture and heat exchanging filter (11), said filter housing having a first opening (12) to be connected to the patient's stoma, and at least one second opening (14) at the opposite side of the filter (11), characterized in that a valve member is provided at said second opening (14) of the filter housing (10) for closing said second opening, said valve member being adapted to be manually closed by means of a finger and to be opened by returning resiliently.

2. Device according to claim 1, characterized in that a rim (16) is provided at said second opening (14) of the filter housing (10) to prevent unintended closing of the valve member.

3. Device according to claim 1 or 2, characterized in that the valve member comprises a lid (18) having a central pin (19), and a spring (22) between the lid and the filter (11).

4. Device according to claim 3, characterized in that the spring (22) is shaped as a cross having at least one pair of radially opposite arms (24) in one plane, which engage the filter (11), and at least one pair of radially opposite curved arms (25) which are directed upwards away from the filter.

5. Device according to any of claims 1 to 4, characterized in that the filter housing (10), the lid (18) and the pin (19) are made of polyethylene or polypropylene.

6. Device according to any of claims 1-5, characterized in that the spring (22) is made of acetaldehyde resin.

7. Device according to any of claims 1-6, characterized in that the filter (11) is made of foamed polyurethane.

8. Device according to any of claims 1-7, c h a r a c t e r i z e d in that the filter (11) is impregnated with lithium chloride or potassium chloride.

FIG. 1

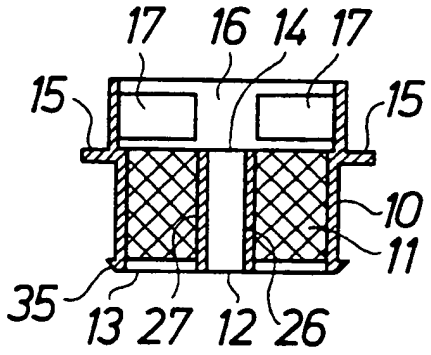


FIG. 2

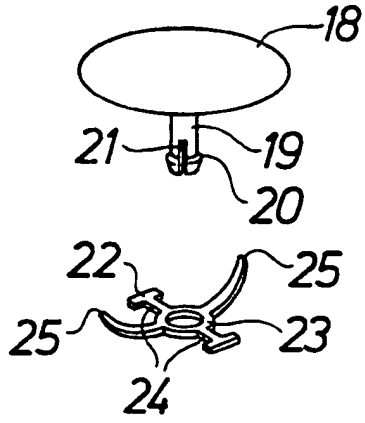
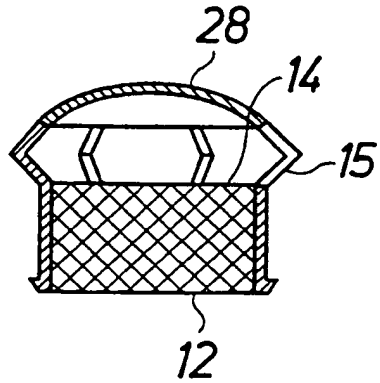


FIG. 3



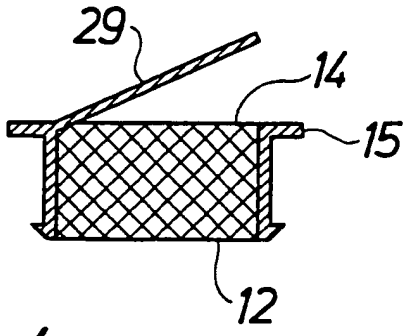


FIG. 4

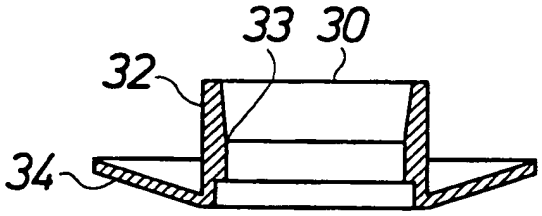


FIG. 5

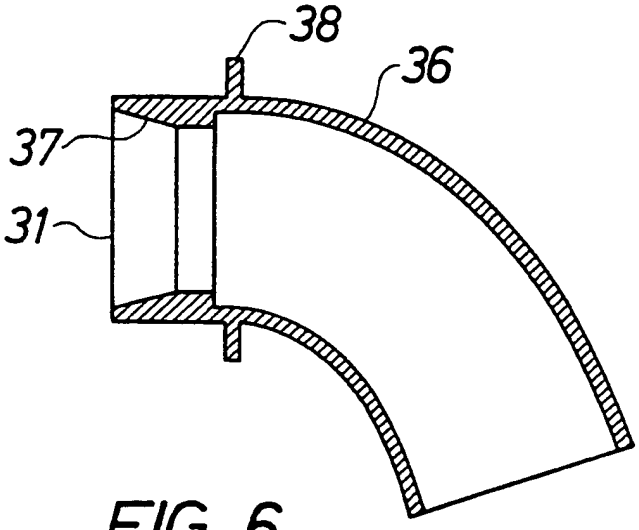


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 94/01229

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/20, A61M 16/04
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	WO, A1, 9308860 (BEZICOT, ROBERT), 13 May 1993 (13.05.93), figure 1, abstract --	1,7
A	DE, A1, 3436777 (KOSS, WALTER), 25 April 1985 (25.04.85), page 15, line 14 - line 27, figure 11 --	1,3
A	US, A, 4971054 (GILLIS ANDERSSON ET AL), 20 November 1990 (20.11.90), column 1, line 42 - column 2, line 19, figure 1 --	1-2

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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International application No.
PCT/SE 94/01229

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5259378 (JEAN-MICHEL HUCHON ET AL), 9 November 1993 (09.11.93), column 3, line 29 - line 58, figures 2-3	1-2

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INTERNATIONAL SEARCH REPORT
Information on patent family members

25/02/95

International application No.
PCT/SE 94/01229

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